

REMARKS

Claims 21-44 are currently pending in the present patent application. Claims 21-28 are cancelled without prejudice to Applicants' rights to pursue such claims in a timely filed continuation or divisional application. Claims 1-20 were cancelled in the Preliminary Amendment filed along with the application on December 21, 2001.

Applicants respectfully request that the amendment be entered in its entirety. In view of the amendment and following remarks, reconsideration and withdrawal of the rejections and objections to the claims in the application is respectfully requested. Applicants believe that the application is now in condition for allowance.

Rejection of Claims 21-44 Under 35 U.S.C. § 103(a) In View of Snowden

The Office Action rejects each of claims 21-44 under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Patent No. 6,214,373, issued to Snowden. As described above, Applicants have cancelled claims 21-28.

Snowden teaches a composition of vitamins and a method for using the composition to treat inflammatory bowel disease (IBD). Vitamin D is included as one of the components of that composition. In Table 2 (column 6, line 57 – column 7, line 11) Snowden particularly lists the vitamin D analog as being cholecalciferol. Cholecalciferol is vitamin D₃. The methods set forth in independent claims 29 and 37 do not use any vitamin D₃ analog. Rather, the methods of independent claims 29 and 37 respectively use 1 α -hydroxyvitamin D₂ and 19-nor-1,25-dihydroxyvitamin D₂. These are both part of the vitamin D₂ family of compounds, rather than the vitamin D₃ family taught by the reference. There is no suggestion in Snowden to combine the teachings of that patent with any other reference that uses a vitamin D₂ analog for any other purpose.

Furthermore, Snowden particularly points out in the background section that persons afflicted with IBD tend to be deficient in iron and zinc and are in need of increased amounts of vitamin C. None of these are the vitamin D compounds of the present invention. In fact, Snowden even teaches away from the use of vitamin D for the treatment of IBD, where column 5, lines 12-16 of this reference states:

Vitamin D, important for maintaining bone mass, is supplemented at 2 times the Daily Value, since it is not optimally absorbed by subjects having IBD, and may be inhibited by steroids used in the treatment of IBD.

This suggests that the incorporation of vitamin D into Snowden's vitamin composition is *not* for the treatment of the IBD, but to help retain bone mass when the patient is taking steroids that cause bone mass depletion during the treatment of the IBD. In the same passage, Snowden also teaches that IBD subjects do not optimally absorb vitamin D. Therefore, Snowden strongly teaches away from the use of vitamin D compounds as a treatment for IBD.

Applicants note that according to § 2143 of the M.P.E.P.,

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure.

Applicants respectfully contend that the Examiner has not established a proper *prima facie* case of obviousness with respect to claims 29-44. As noted above, Snowden does not teach or disclose the use of 1 α -hydroxyvitamin D₂ and 19-nor-1,25-dihydroxyvitamin D₂ for the treatment of IBD. In fact, Snowden teaches away from the use of vitamin D as a treatment for the etiology of the disease. Therefore, because Snowden does not teach each and every limitation of the claims, and there is no suggestion to combine Snowden with another reference that teaches each and every limitation of the claims, Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness and traverse the rejection based upon Snowden.

For the reasons set forth above, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 29-44 for allegedly being obvious over Snowden.

Rejection of Claims 21-44 Under 35 U.S.C. § 103(a) In View of Neef *et al.*

The Office Action rejects each of claims 21-44 under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Patent No. 5,446,035 issued to Neef *et al.* As described above, Applicants have cancelled claims 21-28.

Neef *et al.* claims and discloses 20-methyl-substituted vitamin D derivatives and pharmaceutical compositions of those derivatives. Nowhere does Neef *et al.* teach that the compounds used in the methods of the two remaining independent claims (claims 29 and 37) are suited for use in treating inflammatory disorders such as colitis ulcerosa ileitis terminalis. In fact, Neef *et al.* does not mention nor does it suggest that the vitamin D₂ compounds used in the methods of the present invention, 1 α -hydroxyvitamin D₂ (independent claim 29) and 19-nor-1,25-dihydroxyvitamin D₂ (independent claim 37) are useful in the treatment of inflammatory bowel disease, ulcerative colitis, or any other disorder. Rather, Neef *et al.* is directed to a different class of compounds (i.e. the 20-methyl-substituted vitamin D derivatives). Because Neef *et al.* does not teach each and every limitation of the claims, and there is no suggestion to combine Neef *et al.* with another reference that teaches each and every limitation of the claims, Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness and traverse the rejection based upon Neef *et al.*

For the reasons set forth above, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 29-44 for allegedly being obvious over Neef *et al.*

Conclusion

Applicants respectfully request that the Examiner reconsider and withdraw the rejection of each of claims 29-44 based on the above remarks and amendment. Based on the reasons presented above, Applicants further submit that each of claims 29-44 is allowable and that this application is in condition for allowance. The Examiner is cordially invited to telephone the undersigned at the number listed below if the Examiner believes such would be helpful in advancing the application to issuance.

Respectfully submitted,

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By



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